Australia: Nutritional Supplements

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Summary

Australia is a sophisticated market for nutritional supplements and complementary healthcare products. Products containing herbs, vitamins, and minerals, nutritional supplements, homoeopathic medicines and certain aromatherapy products (those that make therapeutic claims) are referred to as 'complementary medicines'. These also include traditional medicines, such as traditional Chinese medicines (TCM), Ayurvedic medicines and Australian indigenous medicines. Other terms sometimes used to describe complementary medicines include 'alternative medicines', 'natural medicines' and 'holistic medicines'.

These products are regulated as medicines by the Australian Therapeutic Goods Administration (TGA) and must meet the same regulations as pharmaceutical products. As a result, Australia regulates these items more stringently than almost anywhere else in the world.

Market Demand

Complementary medicines and therapies have been widely accepted and used in the Australian community for more than twenty years. Australian consumers are increasingly using a combination of mainstream and complementary medicine to meet their health needs. The current annual retail turnover of complementary medicines is estimated at US$630 million.

Australia's population is approximately 20 million. Industry sources estimate that approximately 52 per cent of the population use at least one non-medically prescribed complementary medicine and that 23 per cent visit at least one complementary healthcare practitioner. Increasingly, Australians are looking for positive health and lifestyle outcomes through the use of complementary medicines, not because of dissatisfaction with conventional medicine, but because they find these healthcare alternatives to be more congruent with their own values, beliefs, and philosophies toward health and life.

Recent studies by industry have indicated that complementary medicine is finding a growing preference amongst patients with chronic or serious diseases who are looking for natural options to assist in the ongoing management of these conditions. This trend is also reflected in a growing acceptance of the use of evidence-based complementary medicines amongst many mainstream heath care providers, and the emergence of greater training in these modalities in undergraduate courses for medicine, pharmacy and nursing.

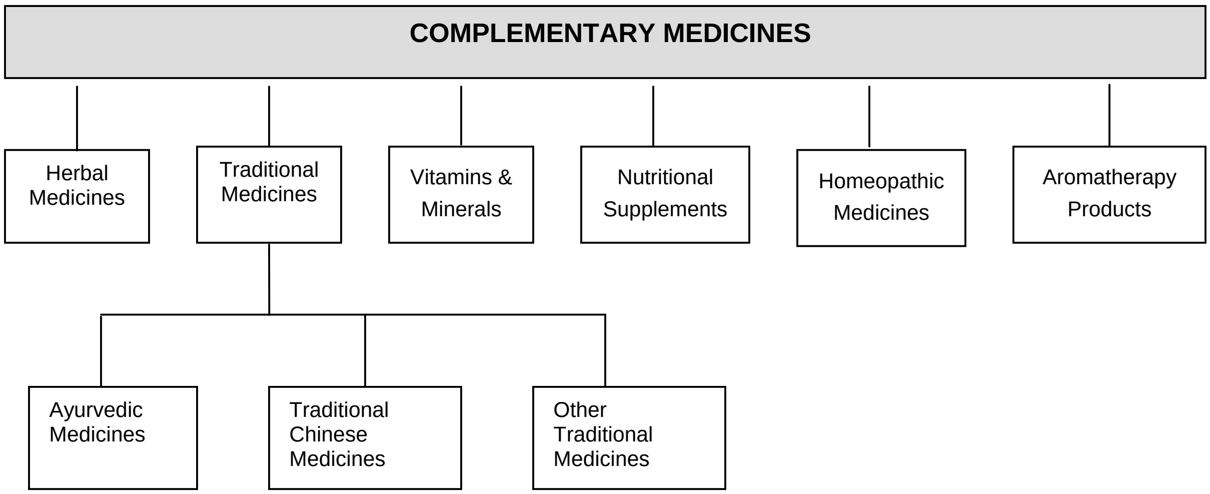
Due to a lack of research on the use of complementary medicines in Australia, it is difficult to determine which is the main source of advice for consumers. However, industry sources indicate that health professionals, including complementary healthcare practitioners, pharmacists and general practitioners, are an important source of advice to consumers about complementary medicines. Most pharmacies sell complementary medicines and pharmacists play an important role in providing advice to consumers.

Market Data

We estimate that the total retail market for dietary supplements is approximately US$630 million.
Australians have a choice of over 17,000 complementary medicines containing around 2,200 active ingredients. Figures released by the Australian Bureau of Statistics in February 2006 from the National Health Survey reflect the growing popularity of complementary healthcare products. They are especially popular among young people with nearly 70 percent of those under the age of 35 years regularly taking complementary medicines. Women are a little more likely to take complementary medicines (57.3 percent) than men (54.8 percent).

Research by industry has found that 74 percent of Australians take at least one complementary health care product in any given year. Australians are increasingly turning to complementary medicines as they seek alternatives to prescription and over-the-counter medicines.

Figure 1: Classes of complementary medicines in Australia



Source: Australian Therapeutic Goods Administration

Distribution Channels

Complementary medicines are available to consumers through a number of different channels. Approximately, 40 percent of dietary supplements are sold through pharmacie, and other channels include supermarkets (23 percent), health food stores (20 percent), herbalist/naturopath (10 percent) and direct to consumer (7 percent).

Pharmacies remain the primary outlet for many complementary medicines and reflects the changing face of pharmacy practice. Pharmacists are becoming more knowledgeable about recommending appropriate complementary medicines and employing in-store naturopaths to meet consumers' needs.

Health food stores are also an important distribution channel for many complementary medicines. However, in recent years, there has been a dramatic increase in the availability of many of the major brands through grocery channels. Products can be found not only within the vitamin and mineral supplement shelves, but complementary medicine variants compete alongside pharmaceutical products within the established medicinal aisles for conditions such as cold and flu, and allergy relief.

Complementary healthcare professionals such as herbalists and naturopaths form another source of distribution, where appropriate medicines will be supplied as a part of a holistic consultation.

Direct to Consumer (DTC) sales also remain a consistent channel for complementary medicines, in particular, the channel serves those brands that only sell through directly as well as mail order companies that provide a wide range of complementary medicine products at discounted prices.

Practitioners

The number and type of healthcare practitioners who supply or provide advice to consumers on complementary medicines is large and varied. The group includes complementary healthcare practitioners such as naturopaths, traditional Chinese medicine practitioners, herbalists, and medical practitioners.

Only rough estimates are available on the size and composition of the complementary healthcare workforce. The *1996 Census of Population and Housing* recorded approximately 4700 persons employed in complementary healthcare occupations: 1939 as naturopaths, 1710 as chiropractors, 464 as acupuncturists, 259 as osteopaths and 352 as 'natural therapists not elsewhere covered'.

Best Prospects

Consumer Trends

According to the Complementary Healthcare Council of Australia, baby boomers are expected to fuel the growth of complementary medicine sales well into the 21st century. Already attuned to alternative approaches to health, baby boomers will increasingly demand greater choice when it comes to healthcare. Baby boomers are expected to be more discerning, have greater spending power and be more concerned with staying healthy. Australia has an ageing population and baby boomers, Australia's largest population group, started turning 60 years old in 2006. The youngest of the baby boomers will reach the age of 65 in 2031. The percentage of the population aged 65 years or older is expected to increase by 25 percent from 2.4 million in 2000 to three million in 2010.

As a result, supplements likely to be used by baby boomers for conditions such as joint pain, sleep, mild depression, energy and stamina, prostate, and brain, joint and heart health will be in demand as this segment of the population seeks to increase their length and quality of life.

As an educated public is choosing health and wellness rather than waiting for illness to strike, strong growth is also being experienced in product categories relating to pregnancy, sports nutrition, cold and flu, weight loss, nicotine replacement, fatigue, and stress.

Distributor Trends

The Australian nutritional supplements market is mature and competitive. There are a large number and variety of products seeking to enter the Australian market and distributors are seeking innovative products with clinical substantiation. U.S. manufacturers with innovative products that have clinically substantiated claims are more likely to receive positive interest from Australian distributors.

Key Suppliers

Due to Australia's regulatory environment, approximately ninety five percent of complementary medicines sold in Australia are manufactured by local companies.

The leading suppliers for dietary supplement sales in pharmacies are:

Blackmores (Australian) www.blackmores.com.au
Nature's Own (Australian) www.naturesown.com.au
Natural Nutrition (Australian) www.naturalnutrition.com.au
Caltrate (Wyeth)
Bio Organics (Australian) www.bioorganics.com.au

Market Entry

The regulatory environment for complementary medicines in Australia is complex. Extensive compliance requirements exist to assure the safety, quality and efficacy of products that are offered for sale. Australia considers itself to be at the forefront of complementary medicines regulation and industry suggests that Australia has one of the highest standards in the world, second to Germany.

Australia has a two-tiered regulatory system for medicines, based on risk. Complementary medicines are included on the Australian Register of Therapeutic Goods (ARTG) as Listed (low risk) or Registered medicines (higher risk), depending on the ingredients and claims made. Most complementary medicines are ‘Listed’ in the ARTG and some are ‘Registered’. Listed and Registered medicines are differentiated on the product label by the designation, 'AUST L' or 'AUST R', followed by a unique number.

Good Manufacturing Practice (GMP) for Medicinal Products

Australian manufacturers of medicinal products are required to comply with the **Australian Code of Good Manufacturing Practice (GMP) for Medicinal Products**, which is based entirely on the international standard, **Guide to Good Manufacturing Practices for Medicinal Products**, published by the Pharmaceutical Inspection Cooperation Scheme (PIC/S). The Australian Code applies to all medicines manufactured and sold in Australia, including complementary medicines.

For overseas manufacturers of therapeutic goods, the TGA will need to verify that the manufacturer has a similar level of GMP to that required in Australia. In the case of U.S. manufacturers the TGA can accomplish this in two ways:

- by a physical inspection of the U.S. manufacturer’s facilities by TGA auditors; or
- by accepting the results of a GMP audit carried out by the FDA

In the second instance, an acceptable rating on the FDA FACTS database for the relevant profile class (product type or manufacturing process) and given within the last three years will be considered equivalent to a GMP certificate. The TGA has access to the FACTS computer database and will utilize this to verify GMP status as determined by the FDA. However, since the FDA does not regulate complementary medicines to an equivalent standard of GMP, it should be noted that a full FDA audit is required to a pharmaceutical medicine standard.

U.S. companies that do not have pharmaceutical GMP can consider having their products manufactured by a TGA approved and/or pharmaceutical GMP facility in the U.S. or have their products contract manufactured in Australia.

Further information on GMP requirements can be obtained from the TGA’s website:
http://www.tga.gov.au/manuf/gmpsom.htm

Pre-market assessment

The TGA uses risk-based pre-market assessment procedures. A number of factors are taken into consideration. These include:

- the toxicity of the ingredients;
- the dosage form of the medicine;
- whether the medicine is indicated for a serious form of a disease, condition or disorder, or for the treatment, cure, management or prevention of a disease, condition or disorder;
- whether the use of the medicine is likely to result in significant side effects, including interactions with other medicines; and
- whether there may be adverse effects from prolonged use or inappropriate self-medication.

Higher risk products are included on the ARTG as Registered Medicines. Registered complementary medicines are assessed individually for quality, safety and efficacy.

Listed Medicines are low risk medicines and may only contain ingredients that have been evaluated by the TGA to be low risk, must be manufactured by licensed manufacturers in accordance with the principles of GMP and may carry indications only for health maintenance and health enhancement or certain indications for non-serious, self-limiting conditions. Most, but not all, complementary medicines included on the ARTG are Listed medicines. Although Listed Medicines are not assessed individually for efficacy, sponsors must certify to the TGA they hold evidence to support all indications and claims made for their products. This evidence may be audited by the TGA.

Ingredients permitted in Listed Medicines

Listed Medicines may be supplied only if they contain active ingredients that have been evaluated by the TGA and found to be of low risk. A consolidated list of substances that may be used as active ingredients in Listed Medicines, including herbal substances, is available on the TGA's web site: http://www.tga.gov.au/cm/listsubs.htm

Efficacy of Listed complementary medicines

Consistent with low risk, Listed complementary medicines can only make low-level claims on symptomatic relief of conditions (other than serious diseases and disorders), health maintenance, health enhancement and risk reduction. The indications/claims on Listed medicines are not subject to pre-market evaluation at the time of Listing. However, at the time of Listing, sponsors must certify that they hold the evidence to support indications and claims made in relation to Listable goods. The evidence held by Sponsors must be sufficient to substantiate that the indications and claims are true, valid and not misleading.

The TGA has developed guidelines for levels and kinds of evidence to support indications and claims to assist sonsors in determining the level of evidence required to support indications and claims made for complementary medicines.

Further information can be obtained from the TGA's website: http://www.tga.gov.au/docs/html/argcm.htm

Personal Importation

Individuals are permitted to import complementary medicines for their own personal use that have not been approved for use in Australia by the TGA. However, the goods are to be used by that individual or a member of his/her immediate family and are not to be sold or supplied to any other person. An individual can import three months supply per importation and the total quantity per year cannot exceed 15 months supply at the manufacturer's recommended maximum dosage.

Further information can be obtained from the TGA's website:
http://www.tga.gov.au/docs/html/personalimp.htm

Import Duty

There are import duties medicinal products imported into Australia.

Market Issues & Obstacles

Appointment of an Australian Sponsor

Therapeutic goods can only be approved for sale in Australia by the TGA and included in the ARTG by an Australian sponsor. This sponsor will need to take responsibility for the product in Australia. Therefore, U.S. companies need to establish a local identity either through a representative/distributor or by incorporating in Australia.

Herbal Products

Herbal products may be classified as foods, cosmetics or medicines depending on whether the product is intended for therapeutic use and whether claims on the label are therapeutic, cosmetic or food. If the claim is therapeutic, the product is regulated by the TGA. Herbal products classified as food are regulated by the Australian-New Zealand Food Authority (http://www.foodstandards.gov.au/).

Australia New Zealand Therapeutic Products Authority (ANZTPA)

The Australian and New Zealand Governments are working to establish a trans-Tasman regulatory scheme for therapeutic products under a new agency to be known as the Australia New Zealand Therapeutic Products Authority (ANZTPA). The joint agency will replace the Australian Therapeutic Goods Administration (TGA) and the New Zealand Medicines and Medical Devices Safety Authority (Medsafe). The proposed joint regulatory scheme would harmonize the regulation of therapeutic products, including complementary medicines, in Australia and New Zealand.

Trade Events

Many Australian distributors of complementary medicines attend major U.S. trade shows and conferences.

Examples of such events include:

Natural Products Expo West
March 9-11, 2007
http://www.expowest.com

Events in Australia include:

The Natural Healthcare Expo
April 20-22, 2007
Sydney Convention & Exhibition Centre
www.naturalhealthcareexpo.com.au

Resources & Key Contacts

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Email: tga-information-officer@health.gov.au
Website: www.tga.gov.au/cm/cm.htm

For More Information

The U.S. Commercial Service in Sydney, Australia can be contacted via e-mail at: Monique.Roos@mail.doc.gov Phone: +61 2 9373 9210; Fax: +61 2 9221 0573; or visit our website: www.buyusa.gov/australia.

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